

REMARKS

The Official Action dated March 6, 2003, together with the telephone conference with Examiner D.C. Jones held on May 6, 2003, have been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

Applicants appreciate the telephone interview granted on May 6 with Examiner D.C. Jones. Proposed amendments were discussed, and the present amendments and remarks reflect those discussions.

Accordingly, by the present Amendment, claims 1 and 45 have been amended to clarify that functionally available cyclodextrin is cyclodextrin which is either uncomplexed, or complexed with material having a cyclodextrin complexation constant less than about 500 M⁻¹, as taught in the specification at page 3, lines 29-32.

It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested. Claims 1-52 are now pending.

35 U.S.C. § 103

Claims 1-45 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Canadian publication "*A spectral displacement study of the binding constants of cyclodextrin-hydrocarbon and -fluorocarbon surfactant inclusion complexes*", Can. J. Chem. 75: 927-933 (1997) by Wilson et al., in view of U.S. Patent No. 3,959,461 to Laughlin et al, in view of U.S. Patent No. 3,929,678 to Bailey et al., and further in view of U.S. Patent No. 3,299,112 to Bailey et al. Specifically, the Examiner asserts that Wilson teaches a composition which contains cyclodextrin (CD) along with an anionic surfactant, and teaches binding constants of CD inclusion complexes. The Examiner further asserts that Laughlin teaches compositions which contain ethoxylated zwitterionic, anionic and cationic

surfactants, while Bailey '678 teaches quaternary ammonium surfactants and Bailey '112 discloses organosilicon surfactants. The Examiner concludes that because CDs are widely known to encapsulate inclusions, and because Wilson teaches compositions comprising CD, fluorocarbons and anionic surfactants, it would have been obvious to include the surfactants of Laughlin and Bailey in a CD-containing composition, with the motivation provided by optimization of a CD composition.

This rejection is traversed and reconsideration is respectfully requested. The present inventive compositions and methods utilizing them are suitable for capturing unwanted molecules. The compositions comprise functionally available CD, a CD-compatible surfactant and a CD-incompatible surfactant. The functionally available CD is recited as CD present in either uncomplexed form or complexed with materials having a CD complexation constant of less than about $5,000\text{M}^{-1}$. Wilson, on the other hand, as the only cited reference comprising CDs, fails to specify that the CD be functionally available, and fails to disclose the CD as suitable for capturing unwanted molecules. In fact, Wilson suggests CDs only as drug delivery mechanisms. The Wilson study is directed to determining accurate estimates of the binding constants for anionic and fluorocarbon surfactants with CD in order to compare the effects of size, hydrophobicity, conformational effects, and solvation of the surfactant head group, on the binding constants. In other words, Wilson merely teaches CD binding constants and the properties which influence them. There is not a single Wilson exemplar composition which comprise functionally available CDs as recited in the present claims. In fact, all the CDs disclosed by Wilson are bound into complexes with surfactants for purposes of experimentally determining binding affinity correlates.

Applicants do not dispute that binding constants have been determined for CD-surfactants, and, in fact, rely on this fact in defining the present invention. In the present invention, the CD is functionally available, suitable for removing unwanted molecules. CDs

are not functionally available if they are bound with substances which impede their ability to bind with the target molecules. The present invention is not directed to a delivery system, but to a removal system for target molecules. Hence, it is imperative to the functioning of the present invention that the CDs be functionally available for capturing molecules at the time they come into contact with the target substrate, i.e., uncomplexed CD or CD complexed with material having a CD complexation constant of less than about 5000 M⁻¹, i.e., only weakly complexed.

The secondary references, i.e., Laughlin, Bailey and Bailey, merely teach compositions comprising various surfactants and/or quaternary ammonium additives for detergents. They are silent with respect to functionally available CDs or CDs of any kind. Applicants submit that the deficiency of the primary reference with respect to the presently recited "functionally available CD" ingredient, renders the secondary references irrelevant. There is no motivation to combine the references, since there is no explicit or inherent disclosure of functionally available CDs in the primary reference.

In order to render a claimed invention obvious, prior art must enable one skilled in the art to make and use the claimed invention, *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 U.S.P.Q.2d 1481, 1489 (Fed. Cir. 1997). Since the cited references fail to disclose the inventive "functionally available CDs", or to suggest any motivation for selecting them, the reference compositions could not function to remove unwanted molecules from target substrates. Hence, the reference teachings, alone or in combination, do not enable the present inventive compositions or methods utilizing the same. Therefore, the rejection of claims 1-45 under 35 U.S.C. § 103(a) over Wilson in view of Laughlin, Bailey and Bailey, is overcome and reconsideration is respectfully requested.

Obviousness-type Double Patenting

Claims 1-45 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,207,933 to Trinh et al. Specifically, the Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct because Trinh also teaches compositions which contain CD, such as alpha-, beta-, and gamma-CDs and mixtures thereof; glycerol 12-hydroxystearate monoester; various quaternary ammonium containing compounds; and silicones such as polydimethylsiloxanes. Further, the Examiner equates the water-insoluble protective matrix of Trinh with the instantly claimed CD-incompatible surfactant, stating however, that the protective material is different than the CD-perfume complex.

This rejection is traversed and reconsideration is respectfully requested. More particularly, as defined by claim 1, the present invention is directed to compositions suitable for capturing unwanted molecules. The compositions comprise functionally available cyclodextrin, a cyclodextrin-incompatible surfactant, and a cyclodextrin-compatible surfactant. The concentration of functionally available cyclodextrin is at least about 0.001%, and functionally available CD is defined as being either uncomplexed or complexed with material having a CD complexation constant of less than 5,000 M⁻¹.

Trinh, on the other hand, discloses compositions comprising, *inter alia*, water insoluble protected complex particles that tend to separate in the composition. Trinh discloses at column 4, lines 19-32 that the water-insoluble complex particles comprise a protected particulate cyclodextrin/perfume complex. The CD-inclusive complex is protected by encapsulation in a solid, substantially water-insoluble material that melts at a temperature between about 30°C and about 90°C. The nature of the "protective material" is elaborated on at columns 8-9. Thus, the water-insoluble particles of Trinh are cyclodextrin-perfume

complexes encapsulated by a water-insoluble protective matrix, and suspended in the composition.

As discussed with the Examiner during the telephone interview, Applicants submit that the Trinh encapsulated complexes cannot function as the "functionally available CD" of the present invention. The CD compositions of the present invention are capable of removing unwanted molecules from a target substrate. Hence, the CD must be in "functionally available" form, i.e., it must either be uncomplexed, or complexed with material having a CD complexation constant less than about 5000 M⁻¹. The cyclodextrins of Trinh et al, complexed with perfume and bound in an insoluble matrix, are not "functionally available" as required by claim 1. The Trinh CDs are, by definition, complexed with perfume molecules and then encapsulated, preventing the release of the perfume molecules until the encapsulation material melts. It would be impossible for the Trinh CDs to be functionally available or operable to capture and remove unwanted molecules.

In order to render a claimed invention obvious, prior art must enable one skilled in the art to make and use the claimed invention, *Motorola, Inc. v. Interdigital Tech. Corp.*, at 1489, *supra*. The CD in the compositions of Trinh are complexed and bound in such a way as to prevent them from adsorbing or otherwise complexing with any other molecules.

Applicants find no teaching or suggestion in Trinh relating to compositions containing functionally-available cyclodextrin or CD suitable for capturing unwanted molecules. Hence, the teachings of Trinh do not enable one skilled in the art to make CD compositions which capture and remove unwanted molecules. It is therefore submitted that the compositions defined by claims 1-45 are nonobvious over and patentably distinguishable from claims 1-11 of Trinh et al, whereby the rejection under the judicially created doctrine of obviousness-type double patenting has been overcome. Reconsideration is respectfully requested.

Claims 1-45 were also rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 5,942,217 to Woo et al. This rejection is traversed. However, to expedite prosecution, a Terminal Disclaimer is being prepared and will be submitted shortly. This Terminal Disclaimer disclaims the terminal portion of the statutory term of any patent granted on the present application which would extend beyond the expiration date of the full statutory term, as shortened by any Terminal Disclaimer filed prior to grant of U.S. Patent No. 5,942,217. The filing of a Terminal Disclaimer simply serves the statutory function of removing the rejection of double patenting and raises neither presumption nor estoppel on the merits of the rejection. *Quad Environmental Technologies v. Union Sanitary District*, 20 U.S.P.Q.2d 1392 (Fed. Cir. 1991). The terminal disclaimer therefore obviates the rejection of claims 1-45 under the judicially created doctrine of obviousness type double patenting. Reconsideration is respectfully requested.

Finally, Applicants note that claims 46-52 are pending but have not been rejected. It is therefore submitted that these claims are in *prima facie* condition for allowance.

It is believed that the above represents a complete response to the Examiner's rejections under 35 U.S.C. § 103, second paragraph, and the doctrine of obviousness-type double patenting, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

By: 
Denise M. Everett

Registration No. 47,552
DINSMORE & SHOHL LLP
1900 Chemed Center
255 East Fifth Street
Cincinnati, Ohio 45202
(513) 977-8787
Attorney for Applicants

VERSION WITH MARKINGS SHOWING CHANGES MADE

In the Claims:

Claims 1 and 45 are amended to read as follows:

1. (Amended) A composition suitable for capturing unwanted molecules, the composition comprising functionally-available cyclodextrin, a cyclodextrin-incompatible surfactant, and a cyclodextrin-compatible surfactant wherein the concentration of functionally-available cyclodextrin is at least about 0.001%, and the functionally available cyclodextrin is present in an uncomplexed form, or is complexed with material having a cyclodextrin complexation constant of less than about 5,000 M⁻¹.

45. (Amended) A process of manufacturing a composition suitable for capturing unwanted molecules comprising the steps of:

- (a) providing cyclodextrin, a cyclodextrin-compatible surfactant, and a cyclodextrin incompatible surfactant;
- (b) combining said cyclodextrin-compatible surfactant and said cyclodextrin-incompatible surfactant to form a first mixture; and
- (c) subsequently combining said cyclodextrin with said first mixture to form said composition suitable for capturing unwanted molecules;

wherein cyclodextrin is present in the composition in an uncomplexed form, or is complexed with material having a cyclodextrin complexation constant of less than about 5,000 M⁻¹.